

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
WESTERN DIVISION**

CATHERINE S. CRYAN,

Plaintiff,

v.

MONSANTO COMPANY,

Defendant.

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Case No: _____

MONSANTO COMPANY’S ANSWER TO PLAINTIFF’S COMPLAINT

Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Monsanto Company (“Monsanto”), by and through its counsel, respectfully responds by generally denying all allegations contained in plaintiff Catherine S. Cryan’s Complaint and Jury Demand (“the Complaint”), except as set forth below. As defined in the Complaint and as used in this Answer, Monsanto refers to Monsanto Company, a United States based company incorporated in Delaware, and not to other Monsanto-affiliated companies. Silence as to any allegations shall constitute a denial.

1. Monsanto admits the allegations in the first and second sentences of paragraph 1. In response to the allegations in the third sentence of paragraph 1, Monsanto admits that certain of its Roundup[®]-branded products contain POEA and adjuvants, and that the United States Environmental Protection Agency (“EPA”) has classified surfactants and adjuvants as inert.

Monsanto notes that EPA has determined that the surfactants used in Roundup[®]-branded herbicides do not pose an unreasonable risk to human health. In response to the allegations in the final sentence of paragraph 1, Monsanto admits that glyphosate was one of the world's most widely used herbicides in 2013, but notes that Monsanto was and is not the only manufacturer of glyphosate-based herbicides. Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of the specific numbers and statistics cited in the remaining sentences of paragraph 1 and therefore denies those allegations.

2. In response to the allegations in paragraph 2, Monsanto admits that its headquarters are in St. Louis, Missouri, and that it is incorporated in Delaware. Monsanto admits that it and affiliated companies have operations and offices in countries around the world. Monsanto admits that it is a producer of glyphosate-based herbicides but lacks sufficient information regarding the business of other glyphosate producers to admit or deny the allegation as written in the second sentence of paragraph 2. Monsanto admits that it is the leading producer of seeds that contain the Roundup Ready[®] trait and that use of crops with the Roundup Ready[®] trait substantially improves a farmer's ability to control weeds. Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of the specific numbers and statistics provided in the remaining sentences of paragraph 2 and therefore denies those allegations.

3. In response to the allegations in paragraph 3, Monsanto admits that its glyphosate products are registered in at least 130 countries and approved for use on over 100 different crops. Monsanto admits that certain studies have reported that glyphosate is found at *de minimis* levels significantly below regulatory safety limits in various locations and media. Monsanto denies the remaining allegations in paragraph 3.

4. Monsanto admits the allegations in the first sentence of paragraph 4. Monsanto denies the allegations in the second sentence of paragraph 4 to the extent they suggest that the International Agency for Research on Cancer ("IARC") based its evaluation on a complete or accurate assessment of the scientific research regarding glyphosate.

5. Monsanto admits the allegations in the first sentence of paragraph 5. Monsanto denies the allegations in the second sentence of paragraph 5.

6. In response to the allegations in paragraph 6, Monsanto admits that the IARC working group classified glyphosate under Group 2A. Monsanto denies the remaining allegations in paragraph 6.

7. Monsanto denies the allegations in paragraph 7.

8. In response to the allegations in paragraph 8, Monsanto admits that glyphosate repeatedly has been found to be safe to humans and the environment by regulators in the United States and around the world and further admits that it has labeled glyphosate products as approved by regulatory bodies consistent with those findings. Monsanto also admits that the EPA repeatedly has concluded pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) that glyphosate-based herbicides create no unreasonable risk to human health or to the environment when used in accordance with the label. To the extent that paragraph 8 alleges that Monsanto has labeled glyphosate or Roundup[®]-branded herbicides in any manner different or in addition to such regulatory approval, Monsanto denies such allegations.

9. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 9 that plaintiff and/or her employers purchased Roundup[®]-branded products and therefore denies those allegations. The remaining allegations in paragraph 9 set forth conclusions of law for which no response is required. To the extent that a response is deemed required, Monsanto denies the remaining allegations in paragraph 9.

10. The allegations in paragraph 10 set forth conclusions of law for which no response is required.

11. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 11 regarding where the events giving rise to this action occurred and therefore denies those allegations. The remaining allegations in paragraph 11 set forth conclusions of law for which no response is required.

12. Monsanto lacks information or knowledge sufficient to form a belief as to the

truth of the allegations in paragraph 12 and therefore denies those allegations.

13. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 13 and therefore denies those allegations.

14. Monsanto admits the allegations in paragraph 14.

15. In response to the allegations in the first sentence of paragraph 15, Monsanto admits that it discovered the herbicidal properties of glyphosate; that it has manufactured Roundup[®]-branded herbicides; that certain Roundup[®]-branded herbicides contain POEA and adjuvants; and that EPA has classified surfactants and adjuvants as inert. Monsanto notes that EPA has determined that the surfactants used in Roundup[®]-branded herbicides do not pose an unreasonable risk to human health. Monsanto denies the remaining allegations in the first sentence of paragraph 15. In response to the allegations in the second sentence of paragraph 15, Monsanto admits that glyphosate is an herbicide that is used to kill invasive plants and weeds. Monsanto states that the remaining allegations in the second sentence of paragraph 15 are vague and ambiguous and that it lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in the second sentence of paragraph 15 and therefore denies those allegations.

16. Monsanto admits the allegations in the first sentence of paragraph 16. Monsanto denies the allegations in the second sentence of paragraph 16 because the impact of glyphosate on treated plants varies depending upon the amount of glyphosate applied and the type of plant. Monsanto denies the allegations in the third sentence of paragraph 16 to the extent that they suggest that glyphosate is present in any plants at anything other than *de minimis* amounts well within regulatory safety levels, as determined by EPA.

17. In response to the allegations in paragraph 17, Monsanto admits that farmers have safely used Roundup[®]-branded products since the 1970s. Monsanto denies the remaining allegations in paragraph 17.

18. Monsanto admits the allegations in the first two sentences of paragraph 18 and admits that it has marketed Roundup[®]-branded products in accord with EPA's regulatory

determinations under FIFRA. Monsanto otherwise denies the remaining allegations in paragraph 18.

19. In response to the allegations in paragraph 19, Monsanto admits that certain Roundup[®]-branded herbicides contain POEA and adjuvants, that EPA has classified surfactants and adjuvants as inert, and that the specific surfactants and adjuvants used in Roundup[®]-branded herbicides – like those in other manufacturers’ herbicide products – are protected by EPA as “trade secrets.” Monsanto notes that EPA has determined that the surfactants used in Roundup[®]-branded herbicides do not pose an unreasonable risk to human health. Monsanto denies the remaining allegations in paragraph 19.

20. The allegations in paragraph 20 set forth conclusions of law for which no response is required. To the extent that a response is deemed required, Monsanto admits the allegations in paragraph 20.

21. In response to the allegations in paragraph 21, Monsanto admits that EPA requires registrants of herbicides to submit extensive data in support of the human health and environmental safety of their products and further admits that EPA will not register or approve the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. The remaining allegations in paragraph 21 set forth conclusions of law for which no response is required.

22. The allegations in paragraph 22 set forth conclusions of law for which no response is required.

23. Monsanto admits that Roundup[®]-branded products are registered by EPA for manufacture, sale and distribution and are registered by the State of California for sale and distribution.

24. In response to the allegations in paragraph 24, Monsanto admits that EPA requires registrants of herbicides to submit extensive data in support of the human health and environmental safety of their products and further admits that EPA will not register or approve the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. Monsanto states that the term “the product tests” in the final sentence of paragraph 24 is vague and

ambiguous, and Monsanto therefore denies the same. The remaining allegations in paragraph 24 set forth conclusions of law for which no answer is required.

25. Monsanto denies the allegations in paragraph 25 to the extent that they suggest that EPA only evaluates the safety of pesticide products on the date of their initial registration. Monsanto admits that EPA is in the process of conducting regulatory review of various pesticide products, but Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 25 regarding such pesticide products generally and therefore denies those allegations. The remaining allegations in paragraph 25 set forth conclusions of law for which no response is required.

26. In response to the allegations in paragraph 26, Monsanto admits that EPA has undertaken a review of glyphosate and that EPA has not released its findings. Monsanto states, however, that: (a) in September 2016, EPA's Office of Pesticide Programs ("OPP") issued a 227-page evaluation of glyphosate's carcinogenic potential, concluding that "[t]he strongest support is for [the descriptor] 'not likely to be carcinogenic to humans' at doses relevant to human health risk assessment"¹; and (b) at the same time, EPA posted an October 2015 final report by its standing Cancer Assessment Review Committee ("CARC"), in which CARC endorsed EPA's existing classification of glyphosate as "Not Likely to be Carcinogenic to Humans."² Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 26 and therefore denies those allegations.

27. In response to the allegations in paragraph 27, Monsanto admits that an EPA review committee classified glyphosate as Class C in 1985 based on limited data and that EPA

¹ EPA's Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 141 (Sept. 12, 2016) ("EPA OPP Report"), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094>. The EPA OPP Report was prepared in anticipation of an EPA Scientific Advisory Panel meeting on glyphosate's carcinogenic potential.

² Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, *Cancer Assessment Document – Evaluation of the Carcinogenic Potential of Glyphosate* at 10, 77 (Final Report, Oct. 1, 2015) ("EPA CARC Final Report"), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014>.

changed its classification of glyphosate to Group E based upon a full evaluation of the scientific evidence, including but not limited to three animal carcinogenicity studies. Monsanto admits that plaintiff has accurately quoted from one passage in an EPA document in 1991 with respect to the designation of an agent as Group E, but states that EPA repeatedly has concluded that glyphosate does not pose any cancer risk to humans. In addition to the conclusions in the EPA OPP Report and the EPA CARC Final Report discussed above, other specific findings of safety include:

- “In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that shows evidence of non-carcinogenicity for humans—based on the lack of convincing evidence of carcinogenicity in adequate studies.” EPA, *Glyphosate: Reregistration Eligibility Decision (RED) Facts*, 2 (Sept. 1993), <http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf>.
- “No evidence of carcinogenicity.” Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
- “Glyphosate has no carcinogenic potential.” Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- “There is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.” Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).
- “EPA has concluded that glyphosate does not pose a cancer risk to humans.” 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).
- “In 2014, EPA reviewed over 55 epidemiological studies conducted on the possible cancer and non-cancer effects of [g]lyphosate. Our review concluded that this body of research does not provide evidence to show that [g]lyphosate causes cancer and does not warrant any change in the EPA’s cancer classification for [g]lyphosate.” *Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, & Forestry*, 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director of EPA’s Office of Pesticide Programs), <http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4>, at time stamp 55:05 – 56:20.

Monsanto denies the remaining allegations in paragraph 27.

28. In response to the allegations in paragraph 28, Monsanto admits that it – along

with a large number of other companies and governmental agencies – was defrauded by two chemical testing laboratories, and that Monsanto had hired both of these laboratories to conduct testing on glyphosate. Monsanto states that only one of these laboratories was hired to conduct toxicity tests of glyphosate. Monsanto denies that EPA’s registration of glyphosate or any glyphosate-based herbicides is based upon any invalid Industrial Bio-Test (“IBT”) Laboratories studies. To the extent that the allegations in paragraph 28 are intended to suggest that Monsanto was anything other than a victim of this fraud, such allegations are denied.

29. In response to the allegations in paragraph 29, Monsanto admits that IBT Laboratories was hired to conduct toxicity studies in connection with the registration of a Roundup[®]-branded product. Monsanto denies that EPA’s regulatory approval of such product is based upon any fraudulent or false IBT studies.

30. Monsanto denies the allegations in paragraph 30 to the extent they suggest that EPA performed an inspection of IBT Laboratories solely or specifically in connection with studies conducted on glyphosate. Monsanto admits that EPA performed an audit of IBT Laboratories to investigate that laboratory’s fraudulent and/or improper testing procedures in connection with services provided to a broad number of private and governmental entities and that this inspection included a review of studies IBT conducted on glyphosate. Monsanto was one of several pesticide manufacturers who had used IBT test results. The audit found some toxicology studies conducted with the original Roundup[®] herbicide to be invalid. As a result, Monsanto repeated all required studies in accordance with applicable EPA testing guidelines. Monsanto denies that EPA’s registration of glyphosate or any glyphosate-based herbicides is based upon any invalid IBT studies. To the extent that the allegations in paragraph 30 are intended to suggest that Monsanto was anything other than a victim of this fraud, Monsanto denies those allegations.

31. In response to the allegations in paragraph 31, Monsanto admits that three IBT employees were convicted of the charge of fraud, but Monsanto denies that any of the individuals were convicted based upon studies conducted on glyphosate or glyphosate-based

herbicides.

32. In response to the allegations in paragraph 32, Monsanto admits that it – along with numerous other private companies – hired Craven Laboratories as an independent laboratory to conduct residue studies for Monsanto agricultural products. Monsanto admits that it was defrauded by Craven Laboratories and that, as a result, Monsanto repeated the studies conducted at Craven Laboratories at a substantial cost. To the extent that the allegations in paragraph 32 are intended to suggest that Monsanto was anything other than a victim of this fraud, such allegations are denied.

33. Monsanto denies the allegations in paragraph 33.

34. In response to the allegations in paragraph 34, Monsanto admits that Roundup[®]-branded products are highly valued by its customers because of their efficacy and safety. Monsanto also admits that the patent for glyphosate expired in the United States in 2000. The remaining allegations in paragraph 34 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

35. In response to the allegations in paragraph 35, Monsanto admits that following the development of Roundup[®] Ready seeds, it began to sell them in the 1990s and that such seeds are now widely used by farmers in the United States and worldwide. Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of the specific numbers cited in paragraph 35 and accordingly denies those allegations. The remaining allegations in paragraph 35 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

36. In response to the allegations in paragraph 36, Monsanto admits that glyphosate is one of the world's largest herbicides by sales volume, but Monsanto denies any suggestion that it is the only company that sells glyphosate or glyphosate-based herbicides. Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of the specific numbers cited in paragraph 36 and accordingly denies the same. The remaining allegations in paragraph 36 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

37. In response to the allegations in paragraph 37, Monsanto admits that the New York Attorney General filed a lawsuit against Monsanto in 1996 alleging false and misleading advertising of Roundup[®]-branded products. This lawsuit was subsequently resolved without any admission of wrongdoing by Monsanto. Monsanto states that none of the New York Attorney General's allegations related in any way to a purported or alleged risk of cancer. To the extent the subparts purport to quote a document, the document speaks for itself and thus does not require any further answer. The remaining allegations in paragraph 37 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

38. In response to the allegations in paragraph 38, Monsanto admits it entered into an assurance of discontinuance with the New York Attorney General. The assurance speaks for itself and thus does not require any further answer. The remaining allegations in paragraph 38 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

39. Monsanto denies the allegations in paragraph 39.

40. In response to the allegations in paragraph 40, Monsanto admits that the French court ruled that Monsanto had falsely advertised its herbicide Roundup[®] as "biodegradable" and that it "left the soil clean," but denies the allegations in paragraph 40 to the extent that they suggest that this ruling was in any way related to plaintiff's claim here that glyphosate can cause cancer. Monsanto denies the remaining allegations in paragraph 40.

41. In response to the allegations in paragraph 41, Monsanto denies that IARC follows stringent procedures for the evaluation of a chemical agent. Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of the specific numbers cited in paragraph 41, which are not limited as of any specified date, and accordingly denies the same.

42. In response to the allegations in paragraph 42, Monsanto admits that IARC sets forth in its Preamble the procedures that it claims to follow in its carcinogenicity evaluations. Monsanto denies the remaining allegations in paragraph 42.

43. Monsanto denies any suggestion that IARC reviewed the full body of scientific research in conducting its evaluation of glyphosate or that IARC reliably reviewed the studies

that it cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 43 and therefore denies those allegations.

44. Monsanto denies any suggestion that IARC reviewed the full body of scientific research in conducting its evaluation of glyphosate or that IARC reliably reviewed the studies that it cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 44 and therefore denies those allegations.

45. Monsanto denies the allegations in paragraph 45 to the extent that they suggest that IARC had previously assessed glyphosate. Monsanto admits that IARC classified glyphosate as a Group 2A agent in March 2015.

46. In response to the allegations in paragraph 46, Monsanto admits that IARC issued its monograph for glyphosate, Monograph 112, on July 29, 2015, and that a draft of the monograph was prepared by a “working group” of individuals selected by IARC who met over a one-week period in March 2015 to consider glyphosate along with a number of other substances. Monsanto denies the allegation that all members of the working groups are “experts.” Monsanto denies that the working group or anyone at IARC conducted a one-year review of the scientific evidence related to glyphosate or that the working group’s findings reflected a comprehensive review of the latest available scientific evidence. Monsanto also denies that the working group considered all information available in the scientific literature and all data from government reports that are publicly available. Monsanto denies the remaining allegations in paragraph 46.

47. In response to the allegations in paragraph 47, Monsanto denies that the IARC working group considered all of the data in the numerous studies that have been conducted looking at the safety of glyphosate and glyphosate-containing herbicides in human populations or that it reliably considered the studies that it purports to have reviewed, which frequently reach conclusions directly contrary to those espoused by the IARC working group. To the extent the allegations purport to characterize statements made in the IARC monograph for glyphosate, the

statements in that document speak for themselves, but Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of the source of said information and accordingly denies the allegations.

48. The allegations in paragraph 48 are vague and conclusory. To the extent they purport to characterize statements made in the IARC monograph for glyphosate, the statements in that document speak for themselves, but Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of the source of said information and accordingly denies the allegations.

49. In response to the allegations in paragraph 49, to the extent the allegations purport to characterize statements made in the IARC monograph for glyphosate, the statements in that document speak for themselves, but to the extent that this paragraph means that more than *de minimis* amounts of exposure are present, Monsanto denies the allegations in paragraph 49.

50. In response to the allegations in paragraph 50, Monsanto admits that the IARC working group identified a number of case control studies of populations with exposures to glyphosate, but Monsanto denies that any of these studies provide any evidence of a human health concern from such exposures.

51. Monsanto denies the allegations in paragraph 51. The IARC working group concluded that there was only limited evidence of carcinogenicity in epidemiologic studies, which, per IARC's guidelines, means that the working group could not rule out chance, bias or confounding so as to reach any conclusion of an increased risk.

52. In response to the allegations in paragraph 52, Monsanto admits that the working group cited to a study that it concluded provided evidence of chromosomal damage in community residents reported to be exposed to glyphosate, but Monsanto denies that the study supports such a conclusion or that the authors of the study reached such a conclusion.

53. In response to the allegations in paragraph 53, Monsanto admits that the IARC working group purported to make these findings, but denies that the animal carcinogenicity studies of glyphosate in the aggregate provide evidence of a positive trend for or increase in any

of the identified tumors. Monsanto further states that regulatory agencies around the world have reviewed the same animal studies and concluded that they do not provide evidence that glyphosate can cause cancer. Monsanto denies the remaining allegations in paragraph 53.

54. In response to the allegations in paragraph 54, Monsanto admits that the IARC working group purported to make these findings, but denies that the cited studies provide any reliable basis for a finding that any meaningful levels of glyphosate or AMPA are present or persists in human blood or urine. Monsanto denies the remaining allegations in paragraph 54.

55. In response to the allegations in paragraph 55, Monsanto admits that the IARC working group interpreted a selected number of experimental studies as evidence that glyphosate can cause genotoxicity, but Monsanto denies that the working group reliably considered the full body of scientific data on such alleged genotoxic endpoints and denies that the working group reliably interpreted the studies that it selected for consideration. Regulators around the world repeatedly have concluded that glyphosate is not genotoxic. Monsanto denies the remaining allegations in paragraph 55.

56. In response to the allegations in paragraph 56, Monsanto admits that the IARC working group purported to find such effects, but denies that there is any reliable scientific basis for such conclusion. Monsanto denies the remaining allegations in paragraph 56.

57. In response to the allegations in paragraph 57, Monsanto admits that the working group reviewed the findings of an Agricultural Health Study (“AHS”) published in 2005, but denies that the working group characterized that study as supporting an association between glyphosate and the specified cancers. The AHS cohort study did not find a positive association between glyphosate and any type of cancer. Monsanto denies all other allegations in paragraph 57.

58. In response to the allegations in paragraph 58, Monsanto admits that EPA has a technical fact sheet, as part of its Drinking Water and Health, National Primary Drinking Water regulations, relating to glyphosate that predates the IARC March 20, 2015 evaluation, which should be read in context of EPA’s precautionary regulatory mandate and EPA’s consistent

finding that glyphosate does not pose any cancer risk to humans.

59. In response to the allegations in paragraph 59, Monsanto admits that the Northwest Coalition for Alternatives to Pesticides made the identified claims, but denies that the Coalition provides any reliable basis for any conclusions regarding potential health risks from glyphosate. Monsanto notes that a federal district court has characterized this same publication as an “advocacy piece[] published in [a] non-peer-reviewed journal.” *See Arias v. DynCorp*, 928 F. Supp. 10, 24 (D.D.C. 2013).

60. Monsanto states that the term “toxic” as used in paragraph 60 is vague and ambiguous to the extent it is intended to suggest any evidence of carcinogenicity. Monsanto denies the allegations in paragraph 60.

61. In response to the allegations in paragraph 61, Monsanto admits that Julie Marc published the cited study in 2002 and states that the document speaks for itself and does not require a response. To the extent that a response is deemed required, Monsanto denies the allegations in paragraph 61.

62. In response to the allegations in the first sentence of paragraph 62, Monsanto admits that Julie Marc published a study titled “Glyphosate-based pesticides affect cell cycle regulation” in 2004. To the extent that the first sentence of paragraph 62 characterizes the meaning of the cited study, Monsanto denies the allegations in the first sentence of paragraph 62. In response to the remaining allegations in paragraph 62, Monsanto states that the document speaks for itself and does not require a response. To the extent that a response is deemed required, Monsanto denies the remaining allegations in paragraph 62.

63. In response to the allegations in paragraph 63, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 63 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in paragraph 63.

64. In response to the allegations in paragraph 64, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 64

characterizes the meaning of the cited study, Monsanto denies the allegation that the cited studies support the allegation that glyphosate or Roundup[®]-branded products pose any risk to human health and denies the remaining allegations in paragraph 64.

65. In response to the allegations in paragraph 65, Monsanto states that the terms “at all times” and “these studies” are vague and ambiguous, and therefore Monsanto denies those allegations. Monsanto denies the remaining allegations in paragraph 65.

66. Monsanto denies the allegations in paragraph 66.

67. In response to the allegations in paragraph 67, Monsanto admits that the IARC working group’s classification of glyphosate as a Class 2A carcinogen has resulted in ongoing discussions in certain countries regarding the sale of glyphosate-based herbicides, including the Netherlands. Monsanto denies that any final conclusion has been reached in these countries and denies that there is any scientific basis for the concerns raised by the improper IARC classification. Monsanto denies the remaining allegations in paragraph 67.

68. In response to the allegations in paragraph 68, Monsanto admits that the IARC working group classification led an individual government attorney in Brazil to write a letter to the Brazilian regulatory authorities requesting a reevaluation of glyphosate. Monsanto denies the remaining allegations in paragraph 68.

69. In response to the allegations in paragraph 69, Monsanto admits that following the IARC working group classification, in France, all non-professional plant protection products, including but not limited to glyphosate-based products, will be sold behind locked counters (no free sales). Monsanto further admits that the French government has announced that, beginning on January 1, 2019, the sale of non-professional lawn and garden products, including but not limited to non-professional use glyphosate-based products, will be prohibited with certain exceptions. Monsanto denies the remaining allegations in paragraph 69.

70. In response to the allegations in paragraph 70, Monsanto admits that some employees of Bermuda’s government announced an intention to suspend the importation of glyphosate-based herbicides, but Monsanto lacks information sufficient to form a belief as to the

truth of the allegations about whether this suspension took effect and accordingly denies the same. Monsanto denies the remaining allegations in paragraph 70.

71. In response to the allegations in paragraph 71, Monsanto admits that the IARC monograph appears to be the alleged basis for the Sri Lankan government's actions, including the allegation that glyphosate can cause kidney disease. Monsanto further states that the allegations regarding kidney disease found in Sri Lanka are unrelated to plaintiff's allegations regarding claimed carcinogenicity. Monsanto denies the remaining allegations in paragraph 71.

72. In response to the allegations in paragraph 72, Monsanto denies the alleged basis for Colombia's suspension of aerial spraying of glyphosate. Colombia's attorney general has explained that the ban on aerial spraying of illicit coca plantations was a concession to the FARC ("Fuerzas Armadas Revolucionarias de Colombia"), and had nothing to do with alleged safety concerns. As of April 2016, the government of Colombia has resumed manual application of glyphosate on illicit coca crops. A federal district court in the United States excluded plaintiffs' expert testimony purporting to link these same aerial eradication operations with cancer as scientifically unreliable. *See Arias v. DynCorp*, 928 F. Supp. 10 (D.D.C. 2013). Monsanto denies the remaining allegations in paragraph 72.

73. In response to the allegations in paragraph 73, Monsanto admits that California's Office of Environmental Health Hazard Assessment ("OEHHA") published a notice of intent to include glyphosate on its Proposition 65 listing and admits that this notice was not based upon any independent scientific analysis of glyphosate but instead was in response to a section of the Labor Code triggering such action based solely upon the IARC classification. Monsanto further states that OEHHA concluded in 2007, based upon its own independent evaluation of the scientific evidence, that glyphosate is "unlikely to pose a cancer hazard to humans."³ The remaining allegations set forth conclusions of law for which no response is required. To the extent that a response is deemed required, Monsanto denies the allegations in paragraph 73.

³ OEHHA, *Public Health Goal for Glyphosate in Drinking Water* (June 2007), <http://oehha.ca.gov/media/downloads/water/chemicals/phg/glyphg062907.pdf>.

74. The allegations in paragraph 74 set forth conclusions of law for which no response is required.

75. The allegations in paragraph 75 set forth conclusions of law for which no response is required.

76. In response to the allegations in paragraph 76, Monsanto admits that it has brought a lawsuit challenging OEHHHA's notice of intent to include glyphosate on its Proposition 65 list.

77. In response to the allegations in paragraph 77, Monsanto admits that plaintiff accurately quotes from Monsanto's complaint in the referenced lawsuit, and states that Monsanto's complaint in that lawsuit speaks for itself. Monsanto further admits that its lawsuit cites to OEHHHA's 2007 determination based upon its own independent evaluation of the scientific evidence that glyphosate is "unlikely to pose a cancer hazard to humans."⁴ The remaining allegations in paragraph 77 comprise attorney characterizations and are accordingly denied.

78. Monsanto admits the allegations in paragraph 78.

79. In response to the allegations in paragraph 79, Monsanto admits that, on November 12, 2015, the European Food Safety Authority ("EFSA") issued its Renewal Assessment Report (RAR) on glyphosate, in which it concluded that "glyphosate is unlikely to pose a carcinogenic hazard to humans."⁵ Monsanto further admits that this conclusion affirmed a similar finding by the German Federal Institute for Risk Management (BfR). Monsanto admits that the European scientists who reached these determinations were acting independently of Monsanto and were acting to protect the public.

⁴ OEHHHA, *Public Health Goal for Glyphosate in Drinking Water* (June 2007), <http://oehha.ca.gov/media/downloads/water/chemicals/phg/glyphg062907.pdf>.

⁵ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

80. In response to the allegations in paragraph 80, Monsanto denies that “industry groups” were afforded any ability to review the RAR beyond that afforded to the public generally. Monsanto otherwise admits the allegations in paragraph 80.

81. Monsanto admits the allegations in paragraph 81.

82. In response to the allegations in paragraph 82, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto denies the allegations in paragraph 82 to the extent that they purport to set forth all of the distinctions identified by EFSA between its evaluation and the evaluation of the IARC working group. Monsanto states that in the same document cited by plaintiff, EFSA states that, in contrast to IARC, “the EU peer review concluded that no significant increase in tumour incidence could be observed in any of the treated groups of animals in the nine long term rat studies considered” and explains that “[a]s well as reviewing a larger number of studies [than IARC], EFSA for example considered that carcinogenic effects observed at high doses were unreliable as they could be related to general toxicity.”⁶ To the extent that paragraph 82 characterizes the meaning of the cited studies, Monsanto denies the remaining allegations in paragraph 82.

83. In response to the allegations in paragraph 83, Monsanto states that the cited document speaks for itself and does not require a response.

84. In response to the allegations in paragraph 84, Monsanto admits that EFSA set acceptable exposure thresholds for glyphosate that are orders of magnitude higher than those which occur in the ordinary use of glyphosate-based herbicides. Monsanto denies that these exposure thresholds are based upon any alleged risk of carcinogenicity.

85. In response to the allegations in paragraph 85, Monsanto admits that certain individuals, including Dr. Christopher Portier, sent the letter identified in paragraph 85 (hereinafter, “the Portier letter”). Monsanto denies that Dr. Portier or the other signatories to his

⁶ EFSA, *EFSA Explains Risk Assessment Glyphosate*, http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf.

letter are “independent” and “renowned international experts in the field.” Monsanto states that Dr. Portier has been disclosed as an expert witness retained by plaintiffs’ counsel in the glyphosate cancer litigation against Monsanto. Monsanto otherwise admits that this letter urged the EU Health Commissioner to disregard the scientific findings reached by EFSA and by the BfR.

86. In response to the allegations in paragraph 86, Monsanto admits that Dr. Portier sent the letter identified in paragraph 86. Monsanto denies that Dr. Portier or the other signatories to his letter are “renowned international experts in the field.” Monsanto admits that certain members of the IARC working group assigned to glyphosate signed on to the Portier letter, but states that Monsanto lacks information or knowledge sufficient to form a belief as to whether those individuals or the other signatories were aware at the time that Dr. Portier was working as a consultant for plaintiffs’ counsel.

87. In response to the allegations in paragraph 87, Monsanto states that the cited Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr. Portier – who has been disclosed as an expert witness retained by plaintiffs’ counsel in the glyphosate cancer litigation against Monsanto – seeks in his letter to challenge the scientific conclusions reached by EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans.”⁷ To the extent that paragraph 87 characterizes the meaning of the cited document or of EFSA’s evaluation of glyphosate, Monsanto denies the remaining allegations in paragraph 87.

88. In response to the allegations in paragraph 88, Monsanto admits that IARC concluded that the human epidemiologic data provides only “limited evidence of carcinogenicity,” which IARC defines as meaning that “chance, bias, or confounding could not be ruled out with reasonable confidence.”⁸ Monsanto further admits that Dr. Portier – who has

⁷ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

⁸ <http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php>.

been disclosed as an expert witness retained by plaintiffs' counsel in the glyphosate cancer litigation against Monsanto – seeks in his letter to challenge the scientific conclusions reached by EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans.”⁹ In response to the remaining allegations in paragraph 88, Monsanto states that the cited Portier letter speaks for itself and does not require a response. To the extent that paragraph 88 characterizes the meaning of the cited document or of EFSA's evaluation of glyphosate, Monsanto denies the remaining allegations in paragraph 88.

89. In response to the allegations in paragraph 89, Monsanto states that the cited Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr. Portier – who has been disclosed as an expert witness retained by plaintiffs' counsel in the glyphosate cancer litigation against Monsanto – seeks in his letter to challenge the scientific conclusions reached by EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans.”¹⁰ To the extent that paragraph 89 characterizes the meaning of the cited document or of EFSA's and BfR's evaluation of glyphosate, Monsanto denies the remaining allegations in paragraph 89.

90. In response to the allegations in paragraph 90, Monsanto states that the cited Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr. Portier – who has been disclosed as an expert witness retained by plaintiffs' counsel in the glyphosate cancer litigation against Monsanto – seeks in his letter to challenge the scientific conclusions reached by EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans.”¹¹ To the extent that paragraph 90 characterizes the meaning of

⁹ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

¹⁰ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

¹¹ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

the cited document or of EFSA's and BfR's evaluation of glyphosate, Monsanto denies the remaining allegations in paragraph 90.

91. Monsanto admits the allegations in paragraph 91.

92. In response to the allegations in paragraph 92, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto denies that the self-labeled "consensus statement" represents the view of any consensus of scientific opinion. To the extent that paragraph 92 characterizes the scientific evidence regarding the safety of glyphosate-based herbicides, Monsanto denies the remaining allegations in paragraph 92.

93. In response to the allegations in paragraph 93, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto denies that the self-labeled "consensus statement" represents the view of any consensus of scientific opinion. To the extent that paragraph 93 characterizes the scientific evidence regarding the safety of glyphosate-based herbicides, Monsanto denies the remaining allegations in paragraph 93.

94. In response to the allegations in paragraph 94, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto denies that the self-labeled "consensus statement" represents the view of any consensus of scientific opinion. To the extent that paragraph 94 characterizes the scientific evidence regarding the safety of glyphosate-based herbicides, Monsanto denies the remaining allegations in paragraph 94.

95. In response to the allegations in paragraph 95, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto denies that the self-labeled "consensus statement" represents the view of any consensus of scientific opinion. To the extent that paragraph 95 characterizes the scientific evidence regarding the safety of glyphosate-based herbicides, Monsanto denies the remaining allegations in paragraph 95.

96. In response to the allegations in paragraph 96, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto denies that the self-labeled "consensus statement" represents the view of any consensus of scientific opinion. To the

extent that paragraph 96 characterizes the scientific evidence regarding the safety of glyphosate-based herbicides, Monsanto denies the remaining allegations in paragraph 96.

97. In response to the allegations in paragraph 97, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto denies that the self-labeled “consensus statement” represents the view of any consensus of scientific opinion. To the extent that paragraph 97 characterizes the scientific evidence regarding the safety of glyphosate-based herbicides, Monsanto denies the remaining allegations in paragraph 97.

98. In response to the allegations in paragraph 98, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto denies that the self-labeled “consensus statement” represents the view of any consensus of scientific opinion. To the extent that paragraph 98 characterizes the scientific evidence regarding the safety of glyphosate-based herbicides, Monsanto denies the remaining allegations in paragraph 98.

99. In response to the allegations in paragraph 99, Monsanto admits that the United States Food and Drug Administration (“FDA”) has authority to enforce pesticide residues and that the FDA announced it would begin testing certain foods for glyphosate residues. In response to the remaining allegations in paragraph 99, Monsanto states that the cited documents speak for themselves and do not require a response.

100. In response to the allegations in paragraph 100, Monsanto admits that the U.S. Government Accountability Office (“GAO”) issued the cited report regarding pesticide residue monitoring programs, but Monsanto denies that the GAO report was limited to glyphosate. In response to the remaining allegations in paragraph 100, Monsanto states that the cited documents speak for themselves and do not require a response. To the extent that paragraph 100 characterizes the meaning of the cited documents, Monsanto denies the remaining allegations in paragraph 100.

101. In response to the allegations in paragraph 101, Monsanto admits that the FDA has authority to enforce pesticide residues and that the FDA announced it would begin testing certain foods for glyphosate residues. In response to the remaining allegations in paragraph 101,

Monsanto states that the cited documents speak for themselves and do not require a response. To the extent that paragraph 101 characterizes the meaning of the cited documents, Monsanto denies the remaining allegations in paragraph 101.

102. In response to the allegations in paragraph 102, Monsanto admits that the FDA has authority to enforce pesticide residues and that the FDA announced it would begin testing certain foods for glyphosate residues. In response to the remaining allegations in paragraph 102, Monsanto states that the cited documents speak for themselves and do not require a response. To the extent that paragraph 102 characterizes the meaning of the cited documents, Monsanto denies the remaining allegations in paragraph 102.

103. Monsanto admits the allegations in paragraph 103.

104. In response to the allegations in paragraph 104, Monsanto states that the cited document speaks for itself and does not require a response.

105. In response to the allegations in paragraph 105, Monsanto lacks information or knowledge sufficient to form a belief as to whether each of the individuals at the referenced meeting were “experts” and therefore denies that allegation. Monsanto admits the remaining allegations in paragraph 105.

106. In response to the allegations in paragraph 106, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 106 characterizes the meaning of the cited document, Monsanto denies the remaining allegations in paragraph 106.

107. In response to the allegations in paragraph 107, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 107 characterizes the meaning of the cited document, Monsanto denies the remaining allegations in paragraph 107.

108. Monsanto admits the allegations in paragraph 108.

109. Monsanto admits the allegations in paragraph 109.

110. Monsanto admits the allegations in paragraph 110.

111. Monsanto admits the allegations in paragraph 111. Monsanto notes that, in March 2017, the European Chemical Agency (“ECHA”) announced that its Committee for Risk Assessment concluded that the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen. *See ECHA, Glyphosate not classified as a carcinogen by ECHA, <https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa>.*

112. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 112 and therefore denies those allegations.

113. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 113 and therefore denies those allegations.

114. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 114 and therefore denies those allegations.

115. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 115 and therefore denies those allegations.

116. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 116 and therefore denies those allegations.

117. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 117 and therefore denies those allegations.

118. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 118 and therefore denies those allegations.

119. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 119 and therefore denies those allegations.

120. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 120 and therefore denies those allegations.

121. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 121 and therefore denies those allegations.

122. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 122 and therefore denies those allegations.

123. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 123 and therefore denies those allegations.

124. Monsanto denies that any exposure to Roundup[®]-branded products can cause non-Hodgkin's lymphoma ("NHL") and other serious illnesses and therefore denies the allegations in paragraph 124. Monsanto states, however, that the scientific studies upon which IARC purported to base its evaluation of glyphosate were all publicly available before March 2015.

125. Monsanto denies that any exposure to Roundup[®]-branded products can cause NHL and other serious illnesses and therefore denies the allegations in paragraph 125. Monsanto states, however, that the scientific studies upon which IARC purported to base its evaluation of glyphosate were all publicly available before March 2015.

126. In response to the allegations in paragraph 126, Monsanto denies that there is any risk of serious illness associated with the use of and/or exposure to Roundup[®]-branded products and glyphosate and denies that Roundup[®]-branded products or glyphosate are injurious to human health. Monsanto states, however, that the scientific studies upon which IARC purported to base its classification were all publicly available before March 2015. The final sentence of paragraph 126 sets forth a conclusion of law for which no response is required.

127. In response to the allegations in paragraph 127, Monsanto denies that exposure to Roundup[®]-branded products and glyphosate is injurious to human health. Monsanto states, however, that the scientific studies upon which IARC purported to base its cancer classification for glyphosate were all publicly available before March 2015. The allegations in paragraph 127 set forth conclusions of law for which no response is required.

128. In response to the allegations in paragraph 128, Monsanto denies that there is any risk of NHL or other serious illness associated with the use of and/or exposure to Roundup[®]-branded products and glyphosate. Monsanto states, however, that the scientific studies upon which IARC purported to base its cancer classification for glyphosate were all publicly available before March 2015. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 128 and therefore denies those allegations.

129. The allegations in paragraph 129 set forth conclusions of law for which no response is required. To the extent that a response is deemed required, Monsanto denies the allegations in paragraph 129. Monsanto states that the scientific studies upon which IARC purported to base its cancer classification for glyphosate were all publicly available before March 2015.

130. In response to the allegations in paragraph 130, Monsanto denies that it concealed any facts related to the human health safety of glyphosate. The remaining allegations in paragraph 130 set forth conclusions of law for which no response is required.

131. Monsanto denies the allegations in paragraph 131.

132. The allegations in paragraph 132 set forth conclusions of law for which no response is required.

133. Monsanto denies the allegations in paragraph 133.

134. The allegations in paragraph 134 set forth conclusions of law for which no response is required. To the extent that a response is required, Monsanto denies the allegations in paragraph 134. Monsanto states that the scientific studies upon which IARC purported to base its cancer classification for glyphosate were all publicly available before March 2015.

135. Monsanto incorporates by reference its responses to paragraphs 1 through 134 in response to paragraph 135 of plaintiff's Complaint.

136. In response to the allegations in paragraph 136, Monsanto admits that plaintiff purports to bring claims for strict liability but denies any liability to plaintiff.

137. Monsanto denies the allegations in paragraph 137.

138. In response to the allegations in paragraph 138, Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations that plaintiff used or was exposed to Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 138.

139. Monsanto denies the allegations in paragraph 139.

140. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 140 concerning the condition of any Roundup[®]-branded product allegedly used by plaintiff or about plaintiff's alleged use of any such product and therefore denies those allegations. The remaining allegations in paragraph 140 set forth conclusions of law for which no response is required.

141. Monsanto denies the allegations in paragraph 141.

142. Monsanto denies the allegations in paragraph 142.

143. Monsanto denies the allegations in paragraph 143 and each of its subparts.

144. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 144 concerning plaintiff's claimed use of or exposure to Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 144, including that Roundup[®]-branded products have "dangerous characteristics."

145. Monsanto denies the allegations in paragraph 145.

146. Monsanto denies the allegations in paragraph 146.

147. Monsanto denies the allegations in paragraph 147.

148. Monsanto denies the allegations in paragraph 148.

149. Monsanto denies the allegations in paragraph 149.

150. Monsanto denies the allegations in paragraph 150.

151. Monsanto denies the allegations in paragraph 151.

In response to the "WHEREFORE" paragraph following paragraph 151, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper.

152. Monsanto incorporates by reference its responses to paragraphs 1 through 151 in response to paragraph 152 of plaintiff's Complaint.

153. In response to the allegations in paragraph 153, Monsanto admits that plaintiff purports to bring a claim for strict liability failure to warn, but denies any liability to plaintiff.

154. Monsanto denies the allegations in paragraph 154.

155. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 155 that plaintiff or other persons or entities purchased Roundup[®]-branded products and therefore denies those allegations. The allegations in paragraph 155 also set forth conclusions of law for which no response is required. Monsanto denies the remaining allegations in paragraph 155.

156. The allegations in paragraph 156 set forth conclusions of law for which no response is required.

157. Monsanto denies the allegations in paragraph 157. All labeling of Roundup[®]-branded products has been and remains EPA-approved and in compliance with all federal requirements under FIFRA.

158. Monsanto denies the allegations in paragraph 158.

159. Monsanto denies the allegations in paragraph 159.

160. Monsanto denies the allegations in paragraph 160.

161. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 161 and therefore denies those allegations.

162. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 162 concerning plaintiff's claimed use of and exposure to Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 162, including that Roundup[®]-branded products have "dangerous characteristics."

163. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 163 and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 163.

164. Monsanto denies the allegations in paragraph 164.

165. Monsanto denies the allegations in paragraph 165.

166. Monsanto denies the allegations in paragraph 166.

167. Monsanto denies the allegations in paragraph 167.

168. Monsanto denies the allegations in paragraph 168.

169. Monsanto denies the allegations in paragraph 169.

170. Monsanto denies the allegations in paragraph 170.

171. Monsanto denies the allegations in paragraph 171.

In response to the “WHEREFORE” paragraph following paragraph 171, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff’s Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s fees as allowed by law and such further and additional relief as this Court may deem just and proper.

172. Monsanto incorporates by reference its responses to paragraphs 1 through 171 in response to paragraph 172 of plaintiff’s Complaint.

173. In response to the allegations in paragraph 173, Monsanto states that the phrase “directly or indirectly” is vague and ambiguous and that Monsanto lacks information or knowledge sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in paragraph 173.

174. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 174 regarding the specific products allegedly purchased or used by plaintiff, and therefore denies the allegations in paragraph 174.

175. The allegations in paragraph 175 set forth conclusions of law for which no response is required.

176. The allegations in paragraph 176 set forth conclusions of law for which no response is required.

177. Monsanto denies the allegations in paragraph 177.

178. Monsanto denies the allegations in paragraph 178.

179. Monsanto denies the allegations in paragraph 179.

180. Monsanto denies the allegations in paragraph 180.

181. Monsanto denies the allegations in paragraph 181. All labeling of Roundup[®]-branded products has been and remains EPA-approved and in compliance with all federal requirements under FIFRA.

182. Monsanto denies the allegations in paragraph 182.

183. Monsanto denies the allegations in paragraph 183.

184. Monsanto denies the allegations in paragraph 184.

185. Monsanto denies the allegations in paragraph 185, including each of its subparts.

186. Monsanto denies the allegations in paragraph 186.

187. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 187 regarding plaintiff's knowledge and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 187, including that intended use of and/or exposure to Roundup[®]-branded products causes any injuries.

188. Monsanto denies the allegations in paragraph 188.

189. Monsanto denies the allegations in paragraph 189.

190. Monsanto denies the allegations in paragraph 190. All labeling of Roundup[®]-branded products has been and remains EPA-approved and in compliance with all federal requirements under FIFRA.

In response to the "WHEREFORE" paragraph following paragraph 190, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper.

191. Monsanto incorporates by reference its responses to paragraphs 1 through 190 in response to paragraph 191 of plaintiff's Complaint.

192. Monsanto denies the allegations in paragraph 192.

193. In response to the allegations in paragraph 193, Monsanto admits that it has sold glyphosate-based herbicides in accordance with their EPA-approved labeling. Monsanto further states that paragraph 193 sets forth conclusions of law for which no response is required. Monsanto denies the remaining allegations in paragraph 193.

194. Monsanto denies the allegations in the first and second sentences of paragraph 194. All labeling of Roundup[®]-branded products has been and remains EPA-approved and in compliance with all federal requirements under FIFRA. Monsanto states that the final sentence of paragraph 194 sets forth conclusions of law for which no response is required.

195. Paragraph 195 sets forth conclusions of law for which no response is required.

196. Monsanto denies the allegations in paragraph 196.

197. Monsanto denies the allegations in paragraph 197 and each of its subparts.

198. The allegations in paragraph 198 set forth conclusions of law for which no response is required.

199. Monsanto states that the allegation in paragraph 199 that Monsanto made an express warranty sets forth a legal conclusion for which no response is required. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 199 and therefore denies those allegations.

200. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 200 and therefore denies those allegations.

201. Monsanto denies the allegations in paragraph 201.

202. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 202 regarding plaintiff's knowledge and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 202.

203. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 203 and therefore denies those allegations.

204. Monsanto denies the allegations in paragraph 204.

205. Monsanto denies the allegations in paragraph 205.

In response to the “WHEREFORE” paragraph following paragraph 205, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff’s Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s fees as allowed by law and such further and additional relief as this Court may deem just and proper.

206. Monsanto incorporates by reference its responses to paragraphs 1 through 205 in response to paragraph 206 of plaintiff’s Complaint.

207. Monsanto denies the allegations in paragraph 207.

208. Monsanto denies the allegations in paragraph 208.

209. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 209 concerning plaintiff’s claimed use of and exposure to Roundup[®]-branded products and the role of plaintiff’s employers and therefore denies those allegations. The remaining allegations in paragraph 209 set forth conclusions of law for which no response is required.

210. Monsanto denies the allegations in paragraph 210. All labeling of Roundup[®]-branded products has been and remains EPA-approved and in compliance with all federal requirements under FIFRA.

211. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 211 regarding plaintiff’s and plaintiff’s employers’ reliance and therefore denies those allegations. The remaining allegations in paragraph 211 set forth conclusions of law for which no response is required.

212. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 212 regarding plaintiff’s and plaintiff’s employers’ reliance and therefore denies those allegations. The remaining allegations in paragraph 212 set forth conclusions of law for which no response is required.

213. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 213 and therefore denies those allegations.

214. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 214 concerning plaintiff's claimed use of or exposure to Roundup[®]-branded products and therefore denies those allegations. The remaining allegations in paragraph 214 set forth conclusions of law for which no response is required.

215. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 215 concerning plaintiff's claimed use of or exposure to Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 215.

216. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 216 concerning the condition of any Roundup[®]-branded product allegedly used by plaintiff or about plaintiff's alleged use of such product and therefore denies the allegations in paragraph 216.

217. Monsanto denies that there is any risk of serious injury associated with or linked to the as-directed use of and/or exposure to Roundup[®]-branded products and/or glyphosate. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 217 concerning plaintiff's or plaintiff's employers' knowledge about Roundup[®]-branded products and therefore denies the remaining allegations in paragraph 217.

218. Monsanto denies the allegations in paragraph 218.

219. Monsanto denies the allegations in paragraph 219.

220. Monsanto denies the allegations in paragraph 220.

In response to the "WHEREFORE" paragraph following paragraph 220, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper.

In response to the allegations in the section entitled "PRAYER FOR RELIEF," Monsanto denies that plaintiff is entitled to the relief sought therein, including any judgment for any

damages, interest, costs, or any other relief whatsoever.

Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied.

SEPARATE AND AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against Monsanto upon which relief can be granted.

2. Plaintiff's claims are barred in whole because plaintiff cannot proffer any scientifically reliable evidence that the products at issue were defective or unreasonably dangerous.

3. Any alleged negligent or culpable conduct of Monsanto, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

4. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

5. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

6. Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Roundup[®]-branded products and/or glyphosate-containing products.

7. Plaintiff's claims are preempted, in whole or in part, because of U.S. EPA findings that glyphosate does not cause cancer in humans and/or because of U.S. EPA-approved product labeling.

8. Plaintiff's claims are barred, in whole or in part, by the doctrine of primary jurisdiction, including by the authority delegated by Congress to the U.S. EPA.

9. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiff's pre-existing medical conditions.

10. The doctrines contained in Restatement (Second) of Torts § 402A, comments j and k, bar plaintiff's claims against Monsanto in whole or in part.

11. Applicable statutes of limitations and/or repose bar plaintiff's claims in whole or in part.

12. Plaintiff's misuse or abnormal use of the product or failure to follow instructions bar plaintiff's claims in whole or in part.

13. If plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from: (a) acts or omissions of persons or entities for which Monsanto is neither liable nor responsible or, in the alternative, Monsanto is entitled to an assessment of the relative degree of fault of all such persons and entities; or (b) resulted from diseases and/or causes that are not related or connected with any product sold, distributed, or manufactured by Monsanto. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiff's alleged injury or damages.

14. Monsanto had no legal relationship or privity with plaintiff and owed no duty to her by which liability could be attributed to it.

15. Monsanto made no warranties of any kind or any representations of any nature whatsoever to plaintiff. If any such warranties were made, which Monsanto specifically denies, then plaintiff failed to give notice of any breach thereof.

16. Plaintiff's claims are preempted in whole or part by the Freedom of Speech Clause of the First Amendment of the U.S. Constitution.

17. Plaintiff's claims for punitive damages are barred because such an award would violate Monsanto's due process, equal protection and other rights under the United States Constitution, the Ohio Constitution, and/or other applicable state constitutions.

18. Plaintiff's claims for punitive damages are barred because plaintiff has failed to allege conduct warranting imposition of such damages under Ohio law and/or other applicable state laws.

19. Plaintiff's claims for punitive damages are barred and/or limited by operation of state and/or federal law.

20. Plaintiff's claims are barred in whole or in part by plaintiff's own contributory/comparative negligence.

21. Plaintiff's claims are barred in whole or in part by plaintiff's own failure to mitigate damages.

22. Plaintiff's claims are barred in whole or in part by the sophisticated user doctrine.

23. Plaintiff's common law claims are abrogated by the Ohio Products Liability Act ("OPLA"), Ohio Rev. Code Ann. §§ 2307.71-2307.80.

24. Plaintiff's recovery, if any, shall be reduced by those payments that plaintiff receives from collateral sources.

25. If plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by a Monsanto product.

26. Plaintiff's claims are barred to the extent that plaintiff asserts claims that are governed by the laws of a state that does not recognize or limit such claims.

27. Monsanto hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

WHEREFORE, Defendant Monsanto demands judgment in its favor and against plaintiff, dismissing plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY TRIAL DEMAND

Monsanto demands a jury trial on all issues so triable.

Dated: August 16, 2017

/s/ David P. Strup

David P. Strup
SHUMAKER, LOOP & KENDRICK, LLP
1000 Jackson Street
Toledo, OH 43604
Telephone: (419) 321-1306
Facsimile: (419) 241-6894
E-Mail: dstруп@slk-law.com
Ohio Bar Registration Number: 0034665

Attorneys for Defendant Monsanto Company

CERTIFICATE OF SERVICE

I certify that on this 16th day of August 2017, a copy of the foregoing Monsanto Company's Answer was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system. I further certify that a true and correct copy of Monsanto Company's Answer was caused to be served upon the following counsel via electronic mail and United States mail:

James G. O'Brien
David W. Zoll
ZOLL & KRANZ, LLC
6620 W. Central Avenue, Suite 100
Toledo, OH 43617
Telephone: (419) 841-9623
Facsimile: (419) 841-9719
E-mail: david@toledolaw.com
E-mail: jim@toledolaw.com

Attorneys for Plaintiff

/s/ David P. Strup
David P. Strup
SHUMAKER, LOOP & KENDRICK, LLP
1000 Jackson Street
Toledo, OH 43604
Telephone: (419) 321-1306
Facsimile: (419) 241-6894
E-Mail: dstrup@slk-law.com
Ohio Bar Registration Number : 0034665

Attorneys for Defendant Monsanto Company